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INTELLECTUAL PROPERTY

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Attention: G.J. McNeice

re: PCT PATENT APPLICATION NO. PCT/NZ2004/000267
From NZ 529177
AGRESEARCH LIMITED
MULTIPLE ACTIVE AGENTS SUCH AS ANTHELMINTICS SUSTAINED RELEASE DELIVERY DEVICE
Our ref: 124199PCX355 / 29 LAS

Please find attached a Demand for further examination of this PCT application.

With the Demand, please find attached replacement pages 7 to 26, replacement Figures 1 to 3, and a marked up copy for the examiner's reference. We request that further examination be undertaken using the amended claims as submitted with this response.

Summary of Amendments

Old claim 1 has been amended to identify that the method is directed towards parasite reduction; use of at least two types of anthelmintic compounds from differing chemical groups; and intra-ruminal bolus application. For clarity, the phrase regarding the duration of release has also been amended.

New claim 2 has been inserted directed to the different anthelmintic compounds

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having differing activities. Basis for this feature may at least be found from the examples which describe a combination of abamectin and albendazole.

New claim 3 has been inserted referring to the rate of release being continuous. This is implied within the original text of the specification as filed and is clarified herein.

Old claims 4, 6, 14, 15 and 22 have been deleted as the subject of these claims are now incorporated within amended claim 1.

Further minor amendments have been made to the remaining claims to clarify the invention claimed and to correct claim numbering and altered dependencies.

Figures 1 to 3 have been amended to includes axis labels.

Related changes have also been made to the specification as indicated in the marked up pages provided herein.

Remarks

In the examiner's first written opinion, the pending claims were rejected as being anticipated and obvious in light of the citations noted in the examiner's written opinion (documents D1 to D6).

It is submitted that the claims as amended are novel and inventive over D1 to D6.

D1 – AU52162/96
This document is specific to canine species and describes a parasite treatment administered as an orally administered tablet once every six weeks. In contrast, amended claim 1 is directed towards an intra-ruminal device (by inference not able to be used in canine species as canines do not have a rumen). Further, the dose / release regime of claim 1 as amended is not disclosed being a daily release of agents over a time period of 3 to 14 days.

Also of note is that the dosage of abamectin described in D1 is only 5 to 15 μg/kg per dose. This is an order of magnitude less than the dosage as claimed in amended claim 9. Clearly, this leads away from the present invention which aims to provide a maximum integral dose to both reduce parasite burden and address parasite resistance.

D2 – Hennesy et al
Hennesy describes a controlled release device for delivery of one active agent at a time. Also described is topical delivery of the macrocylic lactones avermectin and milbemycin. By contrast the present invention method is directed towards release of at least two agents; where these agents are from different chemical groups (claim 1) and activities (claim 2). Further, no disclosure is made in D2 regarding the dose release however it is the inventor's experience that such devices release only a lower dose of agent than that proposed in the present invention.

D3 – Awadzi et al
This document describes a human parasite treatment comprising a tablet taken orally on a daily basis. The trial is split into two stages, the first being ivermectin tablets, and the second, a week later, being albendazole tablets. No disclosure is made of ruminant animal treatment or rumen application. No disclosure is made of the treatment tablet releasing agents over a sustained period of time. Finally no disclosure is made regarding release of two or more anthelmintics concurrently including use of abamectin.

D4 – Grimshaw et al
Grimshaw describes a parasite treatment using two ivermectin compounds. The time period for release of these agents is over a season at a lower dose rate akin to other devices such as the CAPTEC device described in the background section of the specification. D4 dose not describe use of two different anthelmintic compounds from different chemical groups or different activities. D4 does not describe release within 3 to 14 days as in claim 1 nor the effective dose as defined within the present specification. As stated in the background section of the present specification, it is the inventor's experience that long duration release substances such as that described in D4 do not release sufficient agent or agents to not only reduce parasite burden but also prevent parasite resistance occurring.

D5 – Larsen et al
D5 describes a parasite treatment comprising an ivermectin drench along with a controlled release capsule releasing albendazole. In the case of D5, the time period for release varies depending on the agent. Ivermectin is released rapidly as it is a one off dose. The controlled release capsule is described as releasing albendazole over a time period of 100 days. D5 does not describe con-current release of both agents from the one device. Further, D5 does not describe release of both agents over the time period of 3 to 14 days. Further, other macrorocyclic lactones beyond ivermectin are not disclosed. It is submitted that given the different release times, the effective dose as defined in the present specification could not be achieved using the method of D5.

D6 – Anderson et al
D6 describes a parasite treatment for cows comprising a delivery device that releases oxfendazole only at a low dose rate (0.29 or 0.48 mg/kg/day). No disclosure is made regarding release of two or more agents or use of agents with differing chemical groups or activities. Further, the dose rate described in D6 is significantly lower than that expected to achieve a maximum integral dose as in the present invention. For example, not withstanding the fact that there is no second anthelmintic, the release rate of oxfendazole is significantly different to the release rate of albendazole in the present invention (3-5 mg/kg/day). This in itself illustrates that the method of the present invention, must differ to D6.

Given the above, it is submitted that the claims of the invention as amended are novel and inventive over the above citations. This is because none of the above citations describe all of the claimed features nor would the combination of features be immediately obvious to a person skilled in the art from reading the prior art. In fact, it has been the inventor's experience that arriving at the present method has

required significant efforts to address both parasite burden and parasite resistance. Further, administering two anthelmintic compounds in one tablet or bolus does have technical difficulties, hence why prior art methods typically administer differently and separately.

We look forward to receipt of a second written opinion.

We also enclose a bank draft for AU$768.00 as payment for the Demand.

Please confirm receipt of this Demand prior to **24 August 2005**.

If you have any questions on the above please contact me.

Yours sincerely
JAMES & WELLS

Robert J Snoep
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Enclosures: Bank Draft
Replacement pages 7 to 26
Replacement Figures 1 to 3
Marked up copy